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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/845,715 | 04/30/2001 | George Jackowski | 2132.030 | 3820 |

21917 7590 01/13/2003

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| EXAMINER | |
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| LY, CHEYNE D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | 16 |

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/845,715 | JACKOWSKI ET AL. | |
| | Examiner | Art Unit | |
| | Cheyne D Ly | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 09 September 2002 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a biopolymer marker having a sequence identified as SEQ ID NO:1 useful in indicating at least one particular disease state, classified in class 530, subclass 300.

II. Claims 3-9, drawn to a method for evidencing and categorizing at least one disease state, classified in class 702, subclass 19.

III. Claims 10-28 and 33-34, drawn to a diagnostic assay kit and method for determining the presence of the biopolymer marker or analyte thereof and determining risk-assessment, and identifying therapeutic avenues related to a disease state, classified in classes 422 and 436, subclasses 61 and 63. If this Group is elected, then the below summarized specie election is also required.

IV. Claims 29-32, drawn to an antibody that specifically binds a biopolymer including the marker sequence identified as SEQ ID NO:1 or at least one analyte thereof, classified in class 530, subclass 387.1.

V. Claim 35, drawn to a process for regulating a disease state by controlling the presence or absence of a biopolymer including the sequence identified as SEQ ID NO:1 or at least one analyte thereof, classified in class 514, subclass 2.

### SPECIE ELECTION REQUIREMENT FOR GROUP III:

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species A: A method and kit specific for diagnosing a disease state.

Species B: A method and kit specific for identifying therapeutic avenues related to a disease state.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 10-28 of Group III are generic to both species A and B. These species are distinct due to the use and intended goal of each species. A method or kit for diagnosis has the implied intended goal of determining a disease state at a specific point in time. However, a method or kit for identifying therapeutic avenues has the intended goal of generating an agent for a specific treatment. Therefore, the different use and intended goal of each species cause the species to be distinct.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. The inventions of Groups I-V are distinct inventions because they are directed to different chemical types or methods regarding the critical limitations therein. For Group I, the critical feature is a biopolymer marker. For Group II, the critical feature is a method for evidencing and categorizing at least one disease state. For Group III, the critical feature is a diagnostic assay kit and method for determining the presence of the biopolymer marker or analyte thereof and determining risk-assessment, and identifying therapeutic avenues related to a disease state. For Group IV, the critical feature is an antibody produced against the marker having a sequence identified as SEQ ID NO:1. For Group V, the critical feature is a process for regulating a disease state by controlling the presence or absence of a biopolymer including the sequence identified as SEQ ID NO:1 or at least one analyte thereof. Further, it is acknowledged that various processing steps may cause an antibody of the Claims in Group IV and diagnostic kit of Group III to be directed as to its synthesis by a polypeptide set forth in Group I, however, the distinct critical features of each Group of the inventions of the polypeptide, antibodies and diagnostic kits support the undue search burden if they were examined together. Additionally, polypeptide, antibodies, diagnostic kits and their methods of use have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being search separately.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

9. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
1/7/03

ARDIN H. MARSCHEL
PRIMARY EXAMINER